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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,326	02/24/2004	Fredric J. Cohen	X-11057C	9685

25885 7590 03/15/2007

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/15/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/15/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/785,326	COHEN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 145-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 145-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 19 and 145-156 are currently pending and are the subject of this Office Action. Applicant's amendment filed 2/6/2007 adding new claims 153-156 has been entered.

Response to Arguments

Applicant's arguments filed 2/6/2007 have been fully considered but they are not persuasive. Applicants argue that since the '159 application had a pending Office Action with an expired shortened statutory period for reply when the present application was filed, the '159 application was technically, but not statutorily abandoned, on the day the present application was filed. Thus, applicants argue, the payment of a three-month extension of time required to render the '159 application formally active at the time the present case was filed, was a fee required under 37 C.F.R. § 1.17. As such, applicants assert that the Office should have charged the necessary fees at the time the present application was filed.

These arguments are not persuasive because it the applicant's obligation, not the Office's, to maintain copendency between continuing applications. In the instant case, there was no petition under 37 C.F.R. § 1.136 for an extension of time in the '159 case. As such, there was no requirement for the Patent Office to charge any fees required under 37 C.F.R. § 1.17 in the '159 case.

For these reasons and the reasons set forth in the Office Action mailed 11/6/2006, applicants are required to file a petition to revive the '159 application in order for the instant case

to be copending with the '159 application. Until such a petition is filed and granted, the instant case is not entitled to the benefit of the filing dates of previously filed applications.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. § 119(e) or under 35 U.S.C. §§ 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

This application is claiming the benefit of prior-filed Non-provisional application no. 09/931,159, filed 8/16/2001 under 35 U.S.C. § 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed Non-provisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

In the instant case, the '159 application became abandoned on 11/28/2003 due to failure to reply to the Office Action mailed 8/26/2003. No Extension of Time was filed in said application. Because the instant application was filed on 2/24/2004, which is after the date the '159 application became abandoned, the applications were not co-pending and the benefit claim to the '159 application is improper.

Because the instant application is not entitled to the benefit of the '159 application for the reasons discussed *supra*, the continuity of the instant application has been broken. In light of the

above, the earliest effective U.S. filing date of the instant application has been determined to be 2/24/2004 and the prior art rejections set forth in the 11/6/2006 Office Action are maintained and reiterated below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 145-156 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cohen *et al.* (U.S. Patent No. 6,303,634; Issued Oct. 16, 2001).[1]

The instant claims are drawn to a method of reducing the likelihood of incurring or developing estrogen-dependent breast cancer in a post-menopausal woman by administering the hydrochloride salt of raloxifene (Claim 145).

Cohen *et al.* teach a method of preventing breast cancer comprising administering raloxifene and pharmaceutically acceptable salts thereof (Abstract; Figure 1; col. 5, lines 19-38). The term "prevent" when used in conjunction with breast cancer includes reducing the likelihood of incurring or developing breast cancer (col. 5, lines 62-65). Raloxifene is administered for preferably at least 6 months or chronically (col. 8, lines 21-23) in a dose of 0.1 to 1000 mg/day, preferably 60 mg/day (col. 8, lines 24-29). Raloxifene was shown to be effective in reducing the

[1] The office has approved a Terminal Disclaimer over this reference. However, in view of the adjusted priority date afforded the instant application, the '634 patent now qualifies as prior art under 35 U.S.C. § 102(b).

incidence of breast cancer in post-menopausal women, including women with established osteoporosis (col. 11, lines 23-31 and Tables 1-4).

Thus, the reference anticipates the instantly claimed methods of reducing the incidence of breast cancer in post-menopausal woman by administering raloxifene.

Claims 19 and 145-156 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cohen *et al.* (US2002/0019418 A1; Published Feb. 14, 2002).[2]

Cohen *et al.* teach a method for preventing breast cancer in a human comprising administering an effective dose of raloxifene or a pharmaceutically acceptable salt thereof (¶ [0016]). The term "prevent" when used in conjunction with breast cancer includes reducing the likelihood of incurring or developing breast cancer (¶ [0021]). The methods taught in Cohen *et al.* also relate to treating a patient who is at an increased risk of developing breast cancer (¶ [0022]). Raloxifene is administered for preferably at least 6 months or chronically (col. 8, lines 21-23) in a dose of 0.1 to 1000 mg/day, preferably 60 mg/day (¶ [0033]). Raloxifene was shown to be effective in reducing the incidence of breast cancer in post-menopausal women, including women with established osteoporosis (¶ [0049] and Tables 1-4). The methods taught in Cohen *et al.* also include preventing *de novo* breast (Claim 12).

Thus, the reference anticipates the instantly claimed methods of reducing the incidence of breast cancer in post-menopausal woman by administering raloxifene.

[2] U.S. Patent Application Publication of application no. 09/931,159.

Claims 19 and 145-152 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cummings *et al.* (JAMA, 1999, vol. 281, pages 2189-2197) (prior art of record).

Cummings *et al.* discuss the results of a randomized trial wherein raloxifene was administered to postmenopausal women (page 2190, "Subjects") at a dose of 60 mg daily or 120 mg raloxifene daily (page 2190, "Treatment and Randomization"). Patients were followed up every 6 months for 3 years (page 2191, "Ascertainment of Breast Cancer"). The rate of breast cancer in the treatment group was 0.9 (per 1000 woman-years) versus 3.6 (per 1000 woman-years) in the non-treatment group (page 2192, Table 2 and Figure 2). Of the 35 invasive cancer cases, 24 were estrogen-positive and 11 were estrogen-negative. Raloxifene reduced the risk of invasive estrogen receptor-positive breast cancer by 90% (page 2192, "Breast Cancer", third column). The authors conclude that a median of 40 months of treatment with raloxifene decreases the risk of newly diagnosed breast cancer in postmenopausal women who have no history of breast cancer. Further, the effect is largely due to a substantial reduction in the risk of developing estrogen receptor-positive breast cancer (page 2196, last paragraph).
Thus, the reference anticipates the instantly claimed methods of reducing the incidence of breast cancer in post-menopausal woman by administering raloxifene.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

March 7, 2007

PHYLLIS SPIVACK
PRIMARY EXAMINER

3/8/07